

K960509

APR - 4 1996

Surgical Group

Baxter Healthcare Corporation
1500 Waukegan Road
McGaw Park, Illinois 60085 USA

847.473.1500
FAX: 847.785.2460

APR - 4 1996

Baxter

APR - 4 1996

XII. SMDA REQUIREMENTS

**510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
18 GAUGE TRU-CUT BIOPSY NEEDLE**

Manufacturer: Baxter Healthcare Corporation
Surgical Group
400 East Foster Road
Mannford, OK 74044

Regulatory Affairs Contact: Sharon Richter
Surgical Group
1500 Waukegan Road MPK
McGaw Park, IL 60085

Telephone: (847) 785-3311

Date Summary Prepared: January, 1996

Common Name: 18 Gauge Tru-Cut Biopsy Needle

Classification: Class II per 21CFR § 876.1075

Predicate Device: Baxter 14 Gauge Tru-Cut Biopsy Needle

Description: The 18 gauge Tru-Cut Biopsy needle is comprised of a cannula and stylet assembly connected to a handle for ease of insertion into the soft tissue.

XII. SMDA REQUIREMENTS (continued)

**510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
18 GAUGE TRU-CUT BIOPSY NEEDLE**

- Intended Use: The 18 gauge Tru-Cut Biopsy Needle is a device that introduces a cannula into the soft tissue such as breast, lungs, lymph nodes and prostate, etc. for diagnostic evaluation.
- Substantial Equivalence: The Baxter 18 gauge Tru-Cut Biopsy Needle is substantially equivalent to Baxter's 14 gauge Tru-Cut Biopsy Needle in that:
- the intended use is the same
 - the performance attributes are the same
- Summary of testing: All materials used in the fabrication of this 18 gauge Tru-Cut Biopsy Needle were evaluated through biological qualification safety tests as outlined in in ISO 10993 Part-1 "Biological Evaluation of Medical Devices". The biocompatibility tests performed were USP Plastics Class VI, Implant, Hemolysis, Tissue Culture, Pyrogenicity, Ocular Irritation, and Guinea Pig Maximization as required. These materials have met the requirements of the guidance and were found to be acceptable for the intended use.